RECORD AND BRIEFS

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Nos. 15-1039 and 15-1195

In the Supreme Court of the United States

SANDOZ INC., PETITIONER

v.

AMGEN INC., ET AL.

AMGEN INC., ET AL.,
CONDITIONAL CROSS-PETITIONERS

v.

SANDOZ INC.

ON PETITION AND CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTIONS PRESENTED

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) establishes an expedited process for licensing "biosimilar" versions of licensed biologic products ("reference products"). 42 U.S.C. 262(k). In conjunction with that process, the BPCIA establishes a series of steps for the resolution of potential patent claims by the sponsor of the reference product and the biosimilar applicant. § 262(*l*). Among other things, Subsection (*l*)(2)(A) of Section 262 provides that the applicant "shall provide to" the sponsor a copy of the biosimilar application and information about the product's manufacturing processes. Subsection (*l*)(8)(A) provides that the applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

1. The questions presented in the certiorari petition are (a) whether notice of commercial marketing under Subsection (*l*)(8)(A) is legally effective if it is given before Food and Drug Administration (FDA) approval of the biosimilar application, and, if not, (b) whether Subsection (*l*)(8)(A) is a stand-alone requirement that may be enforced by means of an injunction that delays the marketing of the biosimilar until 180 days after FDA approval.

2. The question presented in the conditional cross-petition is whether Subsection (*l*)(2)(A) creates a binding disclosure obligation that a court may enforce by injunction, or whether the sponsor's sole recourse for the applicant's failure to disclose the information is the right, prescribed elsewhere in the BPCIA, to commence an immediate action for patent infringement.

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INTEREST OF THE UNITED STATES

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, both the petition and conditional cross-petition for a writ of certiorari should be granted.

STATEMENT

1. This case concerns the statutory processes in Section 351(*l*) of the Public Health Service Act, 42

U.S.C. 262(*l*) (hereinafter Section 262(*l*)), for facilitating the resolution of certain patent disputes that arise in connection with Food and Drug Administration (FDA) licensing of "biological products" (also known as "biologics") under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, Tit. VII, Subtit. A, §§ 7001-7003, 124 Stat. 804-821.[1]

A "biological product" is "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein * * * , or analogous product * * * applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. 262(i)(1). Biologics may be "isolated from a variety of natural sources—human, animal, or microorganism"—and generally are more complex than drugs that FDA approves under 21 U.S.C. 355. Pet. 2 (citation omitted).

a. Section 262 establishes two routes for biologic licensing. 42 U.S.C. 262(a)(1)(A). First, FDA may license a biologic under Section 262(a) if, *inter alia*, the biologic itself has been demonstrated to be "safe, pure, and potent." § 262(a)(2)(C)(i). Second, the BPCIA provides, in Section 262(k), an abbreviated licensing process generally analogous to the process for approving generic drugs under the Hatch-Waxman Amendments, 21 U.S.C. 355(j). Under Section 262(k), FDA may approve an abbreviated biologic license application (aBLA) if, *inter alia*, the biologic at issue is shown to be "biosimilar" to a previously approved biologic (*i.e.*, the "reference product"). 42 U.S.C. 262(k)(3)(A) and (4)(A)(i); see § 262(i)(2) and (4). Developing a biosimi-

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[1] The BPCIA's primary provisions are codified at 35 U.S.C. 271(e)(2)(C), (4)(D), and (6) and 42 U.S.C. 262(i), (k)-(m).

lar generally is substantially more expensive and time-consuming than developing a generic drug. Pet. 2.

An applicant seeking a license for a follow-on biologic may pursue either of the two routes just described. But if it elects to submit an aBLA, the BPCIA prohibits such an aBLA from being submitted earlier than four years after FDA first licensed the reference product and prohibits FDA from making its approval effective earlier than 12 years after that first licensing of the reference product. 42 U.S.C. 262(k)(7)(A) and (B).

b. A reference product may also be protected by various patents, including product or composition patents, manufacturing-process patents, and method-of-use patents. Without the BPCIA's provisions regarding resolution of patent claims, the litigation of patent claims *before* a biosimilar is licensed and marketed would have faced greater difficulties, because parties litigating such claims, including issues of patent invalidity, would have had to overcome ripeness concerns. Cf. 35 U.S.C. 271(a) (patent infringement includes "mak[ing], us[ing], offer[ing] to sell, or sell[ing] any patented invention").

i. The BPCIA facilitates early resolution of patent claims by establishing a so-called "artificial" patent-infringement claim that may be litigated while FDA reviews an aBLA. Cf. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 675-678 (1990) (discussing "artificial" infringement claims in generic-drug context). Under 35 U.S.C. 271(e)(2)(C), the act of submitting an "application seeking approval of a biological product" is an "act of infringement" if the "purpose of such submission is to obtain approval * * * to engage in the commercial manufacture, use, or sale of a * * * bio-

logical product claimed in a patent or the use of which is claimed in a patent" before the patent expires. 35 U.S.C. 271(e)(2)(C).

ii. Section 262(*l*), in turn, establishes a four-phase process for resolving patent disputes in two rounds of patent litigation between the aBLA applicant (applicant) and the reference-product sponsor (sponsor). See 42 U.S.C. 262(*l*)(2)-(8). This brief refers to those phases as the (1) Information Phase, § 262(*l*)(2); (2) Comprehensive List Phase, § 262(*l*)(3); (3) Round 1 Litigation Phase, § 262(*l*)(4)-(6); and (4) Round 2 Litigation Phase, § 262(*l*)(8) and (9)(A). The BPCIA further provides detailed consequences for failing to follow Section 262(*l*)'s patent-dispute-resolution process. See 35 U.S.C. 271(e)(2)(C) and (6); 42 U.S.C. 262(*l*)(9)(B) and (C). Those consequences, as explained below, can accelerate the timing, and modify the scope, of the ensuing patent litigation.

First, in the Information Phase, the applicant "shall provide to the * * * sponsor," within 20 days of FDA's acceptance of its aBLA for review, both a copy of the aBLA and manufacturing-process information. 42 U.S.C. 262(*l*)(2)(A). The sponsor's "confidential access" to that "information required to be produced pursuant to [Subsection (*l*)](2)" is for the "sole and exclusive purpose" of allowing the sponsor to determine "whether a claim of patent infringement could reasonably be asserted" against the applicant. § 262(*l*)(1)(B)(i) and (D); see § 262(*l*)(1)(H) (authorizing "immediate injunctive relief" for improper disclosure).

If the applicant, however, "fails to provide the application and information required under [S]ection [262](*l*)(2)(A)," the applicant's submission of its aBLA

is deemed an artificial act of infringement. 35 U.S.C. 271(e)(2)(C)(ii). The "sponsor, but not the * * * applicant," may then bring a declaratory-judgment action based on "any patent that claims the biological product or a use of the biological product." 42 U.S.C. 262(*l*)(9)(C). The question presented by respondents' conditional cross-petition (at ii, 31-33) concerns whether, in addition to those express statutory consequences, a court may also compel the applicant to provide the Subsection (*l*)(2)(A) information to the sponsor.

Second, in the Comprehensive List Phase, the sponsor and applicant produce a list of the patents on which infringement claims could reasonably be asserted. 42 U.S.C. 262(*l*)(3). Within 60 days of receiving the applicant's aBLA and manufacturing information, the sponsor "shall provide" to the applicant a list of such patents and identify which patents it would be prepared to license. § 262(*l*)(3)(A). If the sponsor fails timely to include "a patent that should have been included in the list," the sponsor cannot later assert any claim for "infringement of the patent with respect to the [applicant's biosimilar]." 35 U.S.C. 271(e)(6)(C).

Within 60 days after receipt of the sponsor's list, the applicant "may provide" the sponsor with its own list of patents on which it believes a claim of "infringement could reasonably be asserted"; "shall provide" a response to each patent on the sponsor's list explaining why commercially marketing the biosimilar will not violate the sponsor's patent rights; and "shall provide" a response to the sponsor's licensing offer. 42 U.S.C. 262(*l*)(3)(B). Within 60 days after receipt of the applicant's list, the sponsor then "shall provide" the applicant a detailed statement why the patents on the sponsor's list would be infringed and a response

concerning the validity and enforceability of patents on the applicant's list. § 262(*l*)(3)(C).

The applicant's submission of its aBLA is an artificial act of infringement "with respect to a patent that is identified in the list of patents described in section [262](*l*)(3)," *i.e.*, in the Comprehensive List. 35 U.S.C. 271(e)(2)(C)(i). As discussed below, however, other BPCIA provisions control the timing and scope of any resulting patent-infringement claims, which can proceed in two potentially overlapping rounds of litigation.

Third, in the Round 1 Litigation Phase, the applicant and sponsor identify the patents for prompt (Round 1) infringement litigation. 42 U.S.C. 262(*l*)(4)-(6). The applicant and sponsor negotiate which patents from the Comprehensive List should be promptly litigated. If within 15 days they reach agreement on such a "list of * * * patents," the "sponsor shall bring an action for patent infringement with respect to each such patent" within 30 days. § 262(*l*)(4) and (6)(A).

If they do not reach agreement within 15 days, the applicant "shall notify" the sponsor of "the number of patents" that the applicant will designate for its Round 1 list; then within five days, the applicant and sponsor "shall simultaneously" exchange their Round 1 lists. 42 U.S.C. 262(*l*)(5)(A) and (B)(i). The "number of patents listed" by the sponsor for Round 1 litigation may not exceed the number listed by the applicant, although if the applicant lists no patents the sponsor may list one. § 262(*l*)(5)(B)(ii). The sponsor then "shall bring an action for patent infringement" for each patent on the Round 1 lists within 30 days. § 262(*l*)(6)(B).

If the applicant and sponsor successfully complete the actions required of them in the Information, Comprehensive List, and Round 1 Litigation Phases, the sponsor's Round 1 patent action will be filed roughly 250 days or less after FDA accepts the applicant's aBLA for review. See 42 U.S.C. 262(*l*)(2)-(6). But if the sponsor fails to file the Round 1 litigation within the requisite 30-day period, or if its action for infringement of a patent on a Round 1 list is dismissed without prejudice or not prosecuted in good faith, the sponsor's "sole and exclusive" remedy for infringement of such a Round 1 patent is limited to a "reasonable royalty." 35 U.S.C. 271(e)(6)(A) and (B). That effectively grants an applicant that loses a subsequent infringement action a compulsory license for any such Round 1 patent.

Fourth, the Round 2 Litigation Phase covers the non-Round-1 patents, *i.e.*, the remaining patents on the Comprehensive List not included on a Round 1 list. Cf. 42 U.S.C. 262(*l*)(8)(B)(i) and (ii) (remaining patents). The BPCIA normally postpones litigation on the Round 2 patents. Specifically, if the applicant timely provided the sponsor with the information required in Subsection (*l*)(2)'s Information Phase, neither the sponsor nor the applicant may bring a declaratory-judgment action based on a Round 2 patent before the applicant provides advance notice of the first commercial marketing of its biosimilar. § 262(*l*)(9)(A).

Section 262(*l*)(8)(A)—the central provision at issue in the certiorari petition—governs the timing of that notice. It provides that the "applicant shall provide notice" to the sponsor "not later than 180 days before the date of the first commercial marketing of the biological product licensed under [Section 262](k)." 42

U.S.C. 262(*l*)(8)(A). The questions presented in the certiorari petition (at ii) are whether that notice may be given before FDA approval of the biosimilar and, if not, whether a court may enjoin the applicant's marketing of its biosimilar for 180 days after FDA approval.

When such notice is given, the BPCIA's postponement of litigation on the Round 2 patents ends, 42 U.S.C. 262(*l*)(9)(A), allowing the sponsor to bring suit on those patents. In addition, "[a]fter receiving the notice * * * and before * * * the first commercial marketing" of the biosimilar, the "sponsor may seek a preliminary injunction" to enjoin the commercial manufacture or sale of the biosimilar "until the court decides the issue of patent validity, enforcement, and infringement with respect to any [Round 2] patent." § 262(*l*)(8)(B).

Alternatively, even before any notice is given under Section 262(*l*)(8)(A), the BPCIA's postponement of patent litigation terminates if the "applicant fails to complete an action required of [it]" under certain provisions of Section 262(*l*). 42 U.S.C. 262(*l*)(9)(B). Specifically, the "sponsor, but not the * * * applicant," may bring a declaratory-judgment action on any patent on the sponsor's Comprehensive List (including any relevant Round 2 patent) if the applicant "fails" to provide the sponsor with its timely explanation why marketing the biosimilar would not violate the sponsor's rights under patents on the sponsor's list (§ 262(*l*)(3)(B)(ii)); to provide the sponsor timely notice of the applicant's number of Round 1 patents or its Round 1 list (§ 262(*l*)(5)); to provide the Secretary of Health and Human Services with a timely copy of a complaint in the Round 1 litigation

(§ 262(*l*)(6)(C)(i)); or to provide the sponsor the 180-day advance notice of the biosimilar's first commercial marketing (§ 262(*l*)(8)(A)). See § 262(*l*)(9)(B).

2. Respondents have marketed filgrastim under the brand name Neupogen since 1991. Pet. App. 8a. In May 2014, petitioner filed an aBLA seeking FDA approval of a biosimilar filgrastim product (with the trade name Zarxio) that listed Neupogen as its reference product. *Id.* at 8a-9a. On July 7, 2014, FDA notified petitioner that it had accepted the aBLA for review. *Id.* at 8a.

On July 8, 2014, petitioner notified respondents of the filing of petitioner's aBLA and stated that petitioner intended to launch its biosimilar immediately upon FDA approval, which it expected in "Q1/2 of 2015." Pet. App. 8a. Petitioner, however, elected not to provide respondents with a copy of its aBLA or manufacturing-process information under Section 262(*l*)(2)(A). *Ibid.* Petitioner informed respondents that respondents were therefore entitled to sue petitioner for patent infringement. *Ibid.*

3. In October 2014, respondents filed a district court action against petitioner, asserting a patent-infringement claim based on a patent claiming a method of using filgrastim, and an unfair competition law (UCL) and a conversion claim under California law. Pet. App. 9a. Respondents' UCL claim was based on two alleged violations of the BPCIA: petitioner's failure to disclose information required by Section 262(*l*)(2)(A), and its allegedly ineffective advance notice of commercial marketing under Section 262(*l*)(8)(A). *Ibid.* Petitioner counterclaimed for a declaratory judgment on both BPCIA questions and on its contentions that respondents' patent was invalid

and not infringed. *Ibid.* Respondents sought a preliminary injunction based on its state-law claims to prevent petitioner from marketing its biosimilar. *Id.* at 9a-10a, 57a-58a. Respondents subsequently obtained petitioner's aBLA in discovery. *Id.* at 10a.

Later, on March 6, 2015, FDA approved petitioner's aBLA for all approved uses of Neupogen. Pet. App. 8a-9a. That same day, petitioner gave respondents a second, "further notice of commercial marketing." *Ibid.*

Shortly thereafter, the district court denied injunctive relief and granted petitioner partial judgment on the pleadings. Pet. App. 56a-84a. The court concluded that petitioner permissibly declined to provide its aBLA and manufacturing-process information under Section 262(*l*)(2)(A), *id.* at 68a-73a, and permissibly gave notice under Section 262(*l*)(8)(A) before FDA approved its aBLA, *id.* at 73a-76a. The court rejected respondents' UCL claim on those federal-law grounds, *id.* at 77a-78a, and separately rejected respondents' state-law conversion claim, *id.* at 78a-79a. The court subsequently entered a Rule 54(b) partial final judgment on respondents' state-law claims and petitioner's BPCIA counterclaims. *Id.* at 11a.

4. The Federal Circuit granted an injunction pending appeal that prohibited petitioner from marketing Zarxio, Pet. App. 31a, and subsequently affirmed in part, vacated in part, and remanded. *Id.* at 1a-55a.

a. The court of appeals first concluded that petitioner could elect not to disclose its aBLA and manufacturing information under Section 262(*l*)(2)(A), subject only to the patent-litigation consequences specified in the BPCIA. Pet. App. 12a-18a. Although Section 262(*l*)(2)(A) states that the applicant "shall" pro-

vide that information, the court concluded that that word and related statutory language must be understood in their broader statutory context. *Id.* at 14a-15a. Other BPCIA provisions in 35 U.S.C. 271(e)(2)(C)(ii) and 42 U.S.C. 262(*l*)(9)(C), the court explained, not only "explicitly contemplate" that the applicant might not provide that information, but also "specifically set[] forth the consequences for such failure: the [sponsor] may bring an infringement action," and the applicant is prohibited from bringing its own "action on patents that claim the biological product or its use." Pet. App. 15a-17a. Given that the BPCIA does not "specify any non-patent-based remedies" for failing to comply with Section 262(*l*)(2)(A), the court concluded that the sponsor's only recourse is to pursue a patent action, in which the sponsor can then "access the required information through discovery." *Id.* at 17a-18a. Judge Newman dissented from that holding. *Id.* at 32a-42a.

b. The court of appeals concluded, however, that an aBLA applicant must give notice of the date of first commercial marketing under Section 262(*l*)(8)(A) *after* FDA approves the applicant's aBLA. Pet. App. 18a-26a. The court reasoned that the requirement to give notice 180 days before the first commercial marketing of the applicant's "biological product licensed under [Section 262](k)," 42 U.S.C. 262(*l*)(8)(A), contemplates that the biosimilar must be "licensed" before the notice is given. Pet. App. 20a-21a. The court believed that the "purpose of [Section 262](*l*)(8)(A) is clear": "to allow the [sponsor] a period of time to assess and act upon its patent rights." *Id.* at 25a-26a. The court then "extended" its injunction forbidding the marketing of Zarxio until September 2, 2015, *i.e.*, 180 days

after petitioner gave its second notice to respondents. *Id.* at 27a-28a, 31a.

Judge Chen dissented from that holding, concluding that petitioner had no independent obligation to provide notice under Section 262(*l*)(8)(A). Pet. App. 42a-55a. That provision, Judge Chen explained, is not a "standalone provision" but rather is a part of "the integrated litigation management process contemplated in (*l*)(2)-(*l*)(7)," and when, as here, the "applicant fails to comply with (*l*)(2), the provisions in (*l*)(3)-(*l*)(8) cease to matter." *Id.* at 43a.

c. The court of appeals affirmed the dismissal of respondents' UCL claim based on an alleged violation of Section 262(*l*)(2)(A), Pet. App. 26a-27a, and deemed respondents' UCL claim based on petitioner's violation of Section 262(*l*)(8)(A) to be moot in light of the court's extension of its injunction, *id.* at 27a-28a. The court affirmed the dismissal of respondents' conversion claim. *Id.* at 28a-29a.

DISCUSSION

Petitioner challenges (Pet. 22-36) the Federal Circuit's conclusions that an applicant may provide the 180-day advance notice of first commercial marketing of its biosimilar under Section 262(*l*)(8)(A) only *after* FDA has licensed that biosimilar, and that a court may enforce Section 262(*l*)(8)(A) by enjoining the applicant from such marketing until 180 days after the applicant provides that notice. Respondents, in turn, challenge (Cross-Pet. 25-40) the court's determination that where an applicant fails at the outset to provide the sponsor with its aBLA and manufacturing-process information under Section 262(*l*)(2)(A), the sponsor's only recourse under the BPCIA is to bring an immediate patent suit. The court of appeals erred in inter-

preting Subsection (*l*)(8)(A), but it correctly construed Subsection (*l*)(2)(A). The proper interpretation of those provisions has a significant impact on the operation of the BPCIA and the ability of aBLA applicants promptly to bring their biosimilars to the public. And because the provisions are integrally related, the Court should consider all of the questions presented together. Both the certiorari petition and conditional cross-petition therefore should be granted.

A. Providing Notice Of Commercial Marketing Before FDA Approval Is Consistent With Section 262(*l*)(8)(A), And Injunctive Relief Is Not Available For A Failure To Furnish Notice Under That Provision

Section 262(*l*)(8)(A) allows the applicant to give the requisite 180-day advance notice of the first commercial marketing of its biosimilar before FDA has approved the applicant's biosimilar application. But in any event, no federal cause of action exists under which a sponsor could obtain injunctive relief if the applicant fails to give notice as specified in Section 262(*l*)(8)(A).

1. The text and purpose of Section 262(*l*)(8)(A)'s notice provision and the BPCIA's broader statutory context demonstrate that the provision permits an applicant to give advance notice of the first commercial marketing of its biosimilar before FDA has licensed the biosimilar.

a. Section 262(*l*)(8)(A)'s text directly addresses the requisite timing. Notice must be given "not later than 180 days *before* the date of the first commercial marketing." 42 U.S.C. 262(*l*)(8)(A) (emphasis added). That restriction places the only limit on the appropriate timing. Nothing in Section 262(*l*)(8)(A) additionally restricts how soon the applicant may provide notice

after the applicant submits its aBLA to FDA. That straightforward conclusion from the absence of such a further limit is reinforced by the very next sentence of Subsection (*l*)(8), where Congress expressly provided that the sponsor may seek a preliminary injunction to enjoin such marketing "[*a*]*fter* receiving the notice * * * *and before* [the] date of the first commercial marketing," § 262(*l*)(8)(B) (emphasis added).

The Federal Circuit inferred a temporal restriction from the phrase "the date of the first commercial marketing of the biological product licensed under [Section 262](k)," 42 U.S.C. 262(*l*)(8)(A), because, it concluded, the word "licensed" indicates that the notice "must be given only after the product is licensed." Pet. App. 20a-21a. But "licensed" there is most naturally read as describing the biological product at "the *date* of [its] first commercial marketing," § 262(*l*)(8)(A) (emphasis added). And Section 262(*l*)(8)(A) simply requires notice be given "not later than 180 days before th[at] date," *ibid.*, a time at which the product may not yet be licensed. That textual focus on the date upon which actual marketing will occur distinguishes Section 262(*l*)(8)(A) from other provisions, cited by the court of appeals (Pet. App. 20a), that require an entity to communicate its opinion about the possible patent-law implications of a future commercial marketing of the "product that is the subject of the subsection (k) application" (aBLA). See § 262(*l*)(3)(B)(ii)(I) and (C).

Moreover, under the Federal Circuit's reading, the owner of a biosimilar with an effective license could be forced to wait 180 days after FDA has authorized it to commence marketing, even if the sponsor had no arguably valid infringement claim to warrant such delay. The timing of biosimilars' entry onto the market was

a significant issue addressed by the BPCIA, which prohibits FDA from making its approval of an aBLA effective before 12 years after the reference product's first licensure. See 42 U.S.C. 262(k)(7)(A); see also § 262(k)(6), (m)(2)(A), and (3)(A) (expressly granting exclusivity periods). Given the expressly granted exclusivity periods, it is particularly unlikely that Congress would have further delayed biosimilars' marketing in such an indirect manner.

b. The Federal Circuit found its reading preferable because, by requiring that the notice (which triggers Round 2 patent litigation under Section 262(*l*)(9)(A)) be given "*after* FDA licensure," it ensured that any Round 2 litigation would reflect a "fully crystallized controversy." Pet. App. 21a (emphasis added). That rationale runs against Congress's policy judgments in the BPCIA. Congress specifically made the "submi[s-sion]" of the applicant's aBLA ("application") an "act of infringement," 35 U.S.C. 271(e)(2) and (2)(C), to facilitate patent litigation soon after the aBLA's submission, which necessarily occurs before FDA could grant a license. Indeed, a central "part of the [BPCIA's] design" is to afford the applicant significant "control" over "the scope of the [Round 1] litigation," *Amgen Inc.* v. *Apotex Inc.*, 827 F.3d 1052, 1062 & n.3 (Fed. Cir. 2016), petition for cert. pending, No. 16-332 (filed Sept. 9, 2016), by allowing it, for instance, to restrict that litigation to just one patent or, conversely, to expand it to include all relevant patents. See 42 U.S.C. 262(*l*)(5)(B)(i)(I), (ii)(II), and (6)(B); p. 6, *supra*. The BPCIA thus necessarily contemplates that all relevant patents can be placed in Round 1 litigation, litigation that—when the parties follow the schedule in Section 262(*l*)—will commence no later

than roughly 250 days after FDA accepts the aBLA for review. See p. 7, *supra*. The aBLA, morever, may be submitted a full eight years before FDA could grant an effective license. § 262(k)(7)(A) and (B). Accordingly, Congress itself chose to permit patent litigation on *all* relevant patents to commence more than seven years *before* such licensing.

The statutory consequences of failing to take the steps specified in Section 262(*l*)'s patent-dispute process further reflect the purpose of facilitating early litigation of patent claims. If the applicant fails at the outset to provide the sponsor with its aBLA and manufacturing-process information under Subsection (*l*)(2), the applicant loses its right to control the pace and scope of the patent litigation because the sponsor may immediately bring suit on the relevant patents. See 35 U.S.C. 271(e)(2)(C)(ii); 42 U.S.C. 262(*l*)(9)(C); pp. 4-5, *supra*. But if the applicant timely provides that information, the sponsor must then timely identify its Complete List of patents, 42 U.S.C. 262(*l*)(3)(A), lest it forever forfeit its right to assert any claim of infringement based on its patents against the applicant's biosimilar, 35 U.S.C. 271(e)(6)(C). And once the sponsor has identified its Complete List of patents, if the applicant fails to take further actions specified by Section 262(*l*), the BPCIA similarly deprives the applicant of its control over the patent litigation and accelerates its potential pace by authorizing the sponsor to bring suit immediately on all patents on its Complete List. 42 U.S.C. 262(*l*)(9)(B); see pp. 8-9, *supra*.

The Federal Circuit relied on the purported absence of any provision specifically imposing "consequence[s] for[] noncompliance with [Subsection]

(*l*)(8)(A)" that would apply to contexts in which, like here, the applicant has also failed to provide the sponsor information at the outset under Subsection (*l*)(2)(A). Pet. App. 24a-25a. The court correctly noted that the consequence provided in Subsection (*l*)(9)(B) if an applicant does not complete a subsequent action in the multi-step process—*i.e.*, allowing the sponsor immediately to bring suit on all patents on its Complete List—applies only if the applicant initially provided the information required by Subsection (*l*)(2)(A). *Ibid.* But the court failed to recognize that specifically identifying such a consequence for noncompliance with Subsection (*l*)(8)(A) is entirely unnecessary if the applicant failed at the outset to furnish the Subsection (*l*)(2)(A) information. In those circumstances, the BPCIA *already* specifies that the sponsor may bring suit on any relevant patent following such a failure. 35 U.S.C. 271(e)(2)(C)(ii); 42 U.S.C. 262(*l*)(9)(C).

Nor was the Federal Circuit correct that Subsection (*l*)(8)(A)'s notice requirement imposes a "standalone" notice provision in service of a broad purpose of "allow[ing] the [sponsor] a period of time to assess and act upon its patent rights" generally. Pet. App. 25a-26a. The notice serves a more narrowly focused purpose: it triggers a statutory period, ending on the date of the first commercial marketing, during which the sponsor may seek a preliminary injunction to prevent the applicant from engaging in the commercial manufacture or sale of the biosimilar until the court resolves *particular* patent claims. 42 U.S.C. 262(*l*)(8)(B). The patent claims that Subsection (*l*)(8) identifies for resolution are expressly limited to claims involving *Round 2* patents. § 262(*l*)(8)(B)(i) and (ii); cf. § 262(*l*)(9)(A) (commercial-marketing notice lifts

BPCIA's general postponement of litigation of Round 2 patents). Congress concluded that a sponsor should be given a fair chance to litigate the Round 2 patents prior to actual marketing, since the applicant controls the scope of the earlier Round 1 litigation. Subsection (*l*)(8)(A)'s notice requirement therefore is properly viewed as affording the sponsor an adequate opportunity to commence litigation on the Round 2 patents that it previously was prevented from bringing while the applicant was following the process for controlling patent litigation.

But where, as here, the applicant's failure to complete actions required of it by Section 262(*l*) allows the sponsor immediately to institute patent litigation, thereby divesting the applicant of its ability to control the pace and scope of the patent litigation, see 35 U.S.C. 271(e)(2)(C)(ii); 42 U.S.C. 262(*l*)(9)(B) and (C), the special provisions for litigation of Round 2 patents in Subsection (*l*)(8)(B) and (9)(A) lose their significance. Cf. Pet. App. 43a, 48a-49a (Chen, J., dissenting). Even if notice might still be required in those circumstances, as long as the applicant gives notice *at least* 180 days before commercial marketing, as petitioner did here, the sponsor can initiate whatever infringement litigation it wants well before that commercial marketing, and it can do so even if the notice is given at the beginning stages of the regulatory process rather than at the end.

2. The Federal Circuit imposed an injunction to enforce its reading of Section 262(*l*)(8)(A)'s notice requirement. Pet. App. 31a. Although respondents state (Br. in Opp. 29-30) that the court had authority under Rule 8(a) to extend its "injunction pending appeal," that rationale makes little sense because the

court had *resolved* that appeal. The Federal Circuit thus reads its decision here as holding more generally that "an injunction [i]s proper to enforce" Section 262(*l*)(8)(A). *Apotex*, 827 F.3d at 1054, 1060-1061; see *id.* at 1063-1065. That holding is incorrect.

A "private right[] of action to enforce federal law must be created by Congress." *Alexander* v. *Sandoval*, 532 U.S. 275, 286 (2001). "[C]ourts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-287. "[A]n implied cause of action" is recognized "only if the underlying statute can be interpreted to disclose [Congress's] intent to create one." *Stoneridge Inv. Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008). And recognizing a cause of action based on inferred, rather than express, intent is a decidedly "rare step." *Paroline* v. *United States*, 134 S. Ct. 1710, 1725 (2014).

Nothing in the BPCIA creates a cause of action to enforce Section 262(*l*)(8)(A)'s notice provision. The BPCIA's carefully calibrated set of consequences for failing to take actions required under Section 262(*l*)'s patent-dispute process simply modifies the pace and scope of patent-infringement litigation. See pp. 4-5, 7-9, *supra*. The Patent Act's private cause of action for infringement (35 U.S.C. 281), in turn, does not provide for enforcement of Section 262(*l*)(8)(A), because failing to provide notice under Section 262(*l*)(8)(A) does not constitute infringement. See 35 U.S.C. 271. By contrast, Congress did specify the availability of "injunctive relief" for a violation of the confidentiality rules in Section 262(*l*)(1), see 42 U.S.C. 262(*l*)(1)(H), an occurrence that does not halt the ongoing patent-dispute-resolution process. That "carefully crafted and

detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly," *Great-West Life & Annuity Ins. Co.* v. *Knudson*, 534 U.S. 204, 209 (2002) (citation and internal quotation marks omitted), and provides no basis for inferring a private right of action for injunctive or other relief to enforce Section 262(*l*)(8)(A). The sponsor's proper course if notice is not given under Section 262(*l*)(8)(A) is therefore the course contemplated by the BPCIA: an immediate patent-infringement action. See 35 U.S.C. 271(e)(2)(C); 42 U.S.C. 262(*l*)(9)(B).

B. The Sponsor's Recourse If An Applicant Fails To Provide Information Under Section 262(*l*)(2)(A) Is Commencement Of A Patent-Infringement Action

Section 262(*l*)(2)(A) provides that the applicant "shall provide" to the sponsor, within 20 days of FDA's acceptance of its aBLA for review, a copy of the aBLA and manufacturing-process information. 42 U.S.C. 262(*l*)(2)(A). The BPCIA, however, further states that if the applicant "fails to provide the application and information required under [S]ection [262](*l*)(2)(A)," the applicant's submission of its aBLA is deemed an artificial act of infringement, 35 U.S.C. 271(e)(2)(C)(ii), on which the sponsor may bring suit, 35 U.S.C. 281. If the applicant "fails to provide" that information, the "sponsor, but not the * * * applicant," may bring a declaratory-judgment action based on "any patent that claims the biological product or a use of the biological product." 42 U.S.C. 262(*l*)(9)(C). The Federal Circuit held that those BPCIA consequences are exclusive and that, when a sponsor brings its patent action, it may obtain information from the

applicant in discovery. Pet. App. 12a-18a. That holding is correct.

Respondents' conditional cross-petition argues (at 25-32) that the Federal Circuit erred in concluding that Section 262(*l*)(2)(A)'s use of "shall" "does not mean 'must.'" Pet. App. 15a. The government agrees that the Federal Circuit misconceived the relevant inquiry in that respect. But Section 262(*l*)(2)(A) may properly be understood as imposing a mandatory condition for invoking Subsection (*l*)'s patent-dispute framework without concluding that an injunction is available to compel compliance with that condition.

Even if the term "shall" is understood as mandatory, the only consequences for failing to satisfy that condition are those expressly set forth by Congress in the BPCIA. That conclusion flows logically from essentially the same reasons discussed above in connection with Section 262(*l*)(8)(A). See pp. 18-20, *supra*. And as petitioner explains, a sponsor can, after conducting a diligent investigation, file an infringement suit as contemplated by the BPCIA based on any patent it reasonably believes has been infringed, and it may seek additional information regarding that patent claim through discovery. See Cross-Br. in Opp. 21-22.

C. The Petition and Conditional Cross-Petition Present Important Questions Warranting Review

1. The questions presented in the petition and conditional cross-petition address the BPCIA's patent-dispute process that applies to every biosimilar for which FDA approval of an aBLA is sought. Those questions thus are now recurring in other actions pending in various district courts. See, *e.g.*, Pet. 41; Br. in Opp. 33-34. The Federal Circuit exercises ex-

clusive jurisdiction over appeals in any civil action arising under any Act of Congress "relating to patents," 28 U.S.C. 1295(a)(1), and petitioner and respondents agree that no circuit split could arise in this BPCIA context. Br. in Opp. 32; Reply Br. 4.

The questions presented are also sufficiently important to merit the Court's review. "[B]iologic medicines are among the most important pharmaceuticals available today" and "are also among the most expensive, with costs often exceeding tens of thousands of dollars per year."[2] In 2013, biologics accounted for approximately $80 billion in spending in the United States, constituting approximately 25% of all pharmaceutical expenditures. FTC, *Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition*, 78 Fed. Reg. 68,841 (Nov. 15, 2013). The BPCIA represents a carefully calibrated legislative effort to promote innovation and competition in this important field, and the questions presented address core questions governing how the BPCIA operates.

2. This case is an appropriate vehicle through which the Court may resolve those questions, notwithstanding the expiration of the Federal Circuit's injunction in September 2015. Although petitioner is no longer enjoined from marketing Zarxio for allegedly violating Section 262(*l*)(8)(A), see Pet. App. 27a-28a, 31a, petitioner explains (Pet. 36-37) that this case is not moot because the dispute is capable of repetition, yet evading review. Respondents do not appear to

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[2] FTC, *Follow-On Biologics Workshop*, Tr. 8 (Feb. 4, 2014), http://www.ftc.gov/system/files/documents/public_events/171301/140204biologicstranscript.pdf (statement of FTC Chairwoman Edith Ramirez).

dispute that conclusion,[3] and the government concludes that a live controversy continues to exist.

Litigation over Section 262(*l*)(8)(A)'s 180-day advance notice requirement is by its nature "too short to be fully litigated prior to cessation or expiration." *Davis* v. *FEC*, 554 U.S. 724, 735 (2008) (citation omitted). In addition, a "reasonable expectation [exists] that the same complaining party will be subject to the same action again." *Ibid.* (citation omitted). Petitioner is a repeat player in the biosimilar market, Pet. 36-37 & n.10; respondents are industry leaders in "develop[ing] and manufactur[ing] biologic medications";[4] and Section 262(*l*)'s provisions apply to every biosimilar for which FDA approval of an aBLA is sought. Already, in at least one other pending patent action, respondents appear to have alleged an impending Section 262(*l*)(8) violation in connection with petitioner's marketing of another biosimilar. See Compl. at ¶¶ 90, 107, 126, 144, 162, *Immunex Corp.* v. *Sandoz, Inc.*, No. 2:16-cv-1118 (D.N.J.) (filed Feb. 26, 2016). Moreover, the Federal Circuit's exclusive jurisdiction over appeals from actions arising under any Act of Congress "relating to patents," 28 U.S.C. 1295(a)(1), means that the precedential decision in this case will govern the parties' future actions. Cf. *Camreta* v. *Greene*, 563 U.S. 692, 702-703, 709 n.7 (2011) (recognizing ongoing injury from adverse binding precedent governing future actions of litigant who otherwise

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[3] Respondents merely contend that the case is moot because petitioner's second notice was effective under the Federal Circuit's reasoning. Br. in Opp. 26, 28-29. This case, however, concerns whether petitioner's first notice was consistent with the BPCIA.

[4] Amgen, Inc., *Innovation in all we do*, http://www.amgenbiotech.com/manufacturing-innovation.html.

prevailed). Under these circumstances, the case is not moot.

3. Petitioner contends (Cross-Br. in Opp. 24-34) that the Court should not grant the conditional cross-petition because the Section 262(*l*)(2)(A) question the cross-petition presents was resolved in the context of a state-law cause of action. That contention is unpersuasive. The Federal Circuit dismissed respondents' state-law UCL claim "based on [its] interpretation" of the BPCIA, including its view that the BPCIA provides its own exclusive remedies that render UCL relief unavailable. Pet. App. 26a-27a, 29a; see Cross-Reply Br. 10. And the Federal Circuit separately directed the district court to "enter judgment on [petitioner's] counterclaim[]," which sought a declaratory judgment on the proper interpretation of Section 262(*l*)(2)(A). Pet. App. 10a, 31a.

Furthermore, the petition and conditional-cross petition raise interrelated questions concerning the proper operation of Section 262(*l*)'s patent-dispute-resolution process. Given the interlocking nature of the relevant provisions in Section 262(*l*)(2)-(8), granting the conditional cross-petition would ensure that the parties would be able to raise the full set of arguments in support of their positions.

CONCLUSION

The petition and conditional cross-petition for a writ of certiorari should be granted.

Respectfully submitted.

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